DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The 112 Rejection is withdrawn because of the arguments set for in the last reply as well as the discussion during the telephonic interview 12/4/08.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 3, 9, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Botich et al. (USPN 5,407,431), in view of Ericson et al. (US Pub 20010014996 A1) and Skakoon et al. (USPN 4,804,368).

Botich et al. discloses a pre-filled syringe (Col. 11, lines 14-24) with a syringe barrel comprising a flange that has a front and rear surface, wherein the front surface is roughened (Col. 11, lines 14-24, see figure 1) "to provide a greater coefficient of friction". The grooves (83) have a regular patterned of roughness since each groove is roughened and the roughness has a convex and concave pitch over the front surface of the flange because of the valleys and ridges that are formed by the grooves (83). Botich et al. fails to disclose "wherein the cross section of the roughened surface has a roughness of about No. 20 to 1500 as expressed in terms of count of sand paper" and "wherein at least one of the front and rear surface is randomly roughened".

Ericson et al. discloses a wedge clamp type termination for elevator tension members, but more importantly Ericson et al. teaches using sandblasting to raise the coefficient of friction of a surface (paragraph [0036]). Ericson et al. further teaches other methods of increasing the surface friction, which include etching, machining, knurling and other suitable equivalents.

Skakoon et al. discloses an infusion apparatus with a cylinder holder that includes a flange insertion groove that allows all different types of syringes to fit into the cylinder holder (Column 5, line 15-35).

Therefore, at the time of the invention it would have been obvious to use sandblasting as another means of roughening the front surface of the flange to create a greater coefficient of friction between the fingers and thumb because it is well known that there are many methods that can be used to increase surface friction as taught by Ericson et al. By using this method of increasing the coefficient of friction, the cross section of the roughened surface having a roughness of about No. 20 to 1500 as expressed in terms of count of sand paper would be an obvious modification since the range lacks any criticality or special feature and thus such a range would have been obvious to one skilled in the art wishing for a particular roughness and friction.

The examiner would also like to note that by using sandblasting, it would cause random roughening because sand is being blasted into the object, thus causing the sand to be randomly placed into the object due to the force being exerted on the sand, thus creating a random pattern after each injection. This pattern can be controlled and follow a regular pattern if this method is used to form sections of roughened areas, thus

creating a regular pattern from the roughened areas. Ericson et al. also teaches the formation of small ridges and valleys, which further supports the fact that the roughened section will have a convex and concave pitch (paragraph [0036]).

It would also be obvious to combine the teachings of Botich et al. and Ericson et al. with Skakoon et al., because Skakoon et al. discloses the benefit of using an automated infusion apparatus because the apparatus allows for a more precise and accurate way to infuse drugs and treatment into a patient (Column 2, line 48-55).

With regards to claim 14,

Botich et al. discloses a pre-filled syringe (Col. 11, lines 14-24) with a syringe barrel comprising a flange that has a front and rear surface, wherein the front surface is roughened (Col. 11, lines 14-24, see figure 1) "to provide a greater coefficient of friction". The grooves (83) have a regular patterned of roughness since each groove is roughened and the roughness has a convex and concave pitch over the front surface of the flange because of the valleys and ridges that are formed by the grooves (83). Botich et al. fails to disclose "wherein the cross section of the roughened surface has a roughness of about No. 20 to 1500 as expressed in terms of count of sand paper" and "wherein at least one of the front and rear surface is randomly roughened".

Ericson et al. discloses a wedge clamp type termination for elevator tension members, but more importantly Ericson et al. teaches using sandblasting to raise the coefficient of friction of a surface (paragraph [0036]). Ericson et al. further teaches other methods of increasing the surface friction, which include etching, machining, knurling and other suitable equivalents.

Skakoon et al. discloses an infusion apparatus with a cylinder holder that includes a flange insertion groove that allows all different types of syringes to fit into the cylinder holder (Column 5, line 15-35), but fails to disclose roughening the insertion grooves.

Therefore, at the time of the invention it would have been obvious to use sandblasting as the first surface of the flange insertion groove to create a greater coefficient of friction between the flange of the syringe and the delivery infusion pump. . By using the method taught in Ericson of increasing the coefficient of friction, the cross section of the roughened surface having a roughness of about No. 20 to 1500 as expressed in terms of count of sand paper would be an obvious modification since the range lacks any criticality or special feature and thus such a range would have been obvious to one skilled in the art wishing for a particular roughness and friction.
The examiner also believes that it would be obvious to roughen the flange insertion groove for the infusion pump since this will allow for a better fit between the flange and the insertion groove and provide a more stable infusion pattern.

Response to Amendment

3. The affidavit under 37 CFR 1.132 filed 5-15-2008 is insufficient to overcome the rejection of claims based upon the 103 Rejection as set forth in the last Office action because: applicant teaches in this specification the same method and structure as the prior art. The 132 affidavit is not sufficient as it doesn't adequately compare the claim

with the prior art, nor does it provide sufficient evidence regarding the unexpected results.

4.

Response to Arguments

5. Applicant's arguments filed 12/19/08 has been fully considered but are not persuasive.

6. The examiner maintains the rejection because of the fact that it is well known to use sandblasting as a way to increase friction, and if we used sandblasting as an alternative to forming ridges on the flange of the syringe, the modified device would be the same as the claimed invention. The examiner understands that the random roughening provides an extra benefit of providing strength but this is a "new" and unexpected characteristic of known structural limitation, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). The examiner believes that by sandblasting the flange of the syringe or the flange of the insertion groove one of ordinary skill would make a device that would have a roughness equivalent of about number 20 to 1500 as expressed in terms of counts of sand paper, and once this occurs there wouldn't be any unexpected results. The range of roughness is extremely large and one of ordinary skill would understand how to make the flange fall with this range and thus create the same device of the claimed invention. As to the unexpected results, the examiner disagrees that these are unexpected results,

since the examiner disagrees that the presence of a property was not possessed by the prior art. The examiner believes the flange with roughness would have the same results as applicant's invention since Botich has ridges that are used for roughness.

7.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW F. DESANTO whose telephone number is (571)272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Matthew DeSanto

/Matthew F DeSanto/
Primary Examiner, Art Unit 3763